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## **CLAIMS**

- 1. A method of protecting a patient from possible adverse effects of a treatment involving inhibition of the SHH-signalling pathway in the patient, the method comprising suppressing testosterone or its effect in the patient.
- 2. A method of treating a proliferative disease such as cancer in a patient the method comprising inhibiting the SHH-signalling pathway and suppressing testosterone or its effect in the patient.
  - 3. A method according to Claim 1 or 2 wherein the SHH-signalling pathway is inhibited by the administration of cyclopamine or a derivative thereof to the patient.

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- 4. A method according to any one of the preceding claim wherein testosterone is suppressed to castrate levels.
- 5. A method according to any one of the preceding claims wherein testosterone or its effect is suppressed by administering any one or more of a GnRH antagonist, a GnRH agonist, an androgen antagonist or a 5α reductase inhibitor to the patient.
- 6. A method according to any one of the preceding claims wherein the patient is male preferably a post-pubescent male.
  - 7. A method according to any one of Claims 2 to 6 wherein the cancer is a cancer in which SHH-signalling plays a role in its growth and/or differentiation.

- 8. A method according to any one of Claims 2 to 7 wherein the cancer is any of basal cell carcinoma, medulloblastoma, glioblastoma or prostate cancer.
- Use of a compound which suppresses testosterone or its effect in the manufacture of a medicament for protecting a male patient from possible adverse effects of a treatment involving inhibition of the SHH-signalling pathway in the patient.
- 10 10. Use of an inhibitor of the SHH-signalling pathway in the manufacture of a medicament for treating a proliferative disease such as cancer in a patient wherein the patient is administered a compound which suppresses testosterone or its effects in the patient.
- 15 11. Use of a compound which suppresses testosterone or its effects in a patient in the manufacture of a medicament for treating a proliferative disease such as cancer in a patient wherein the patient is administered an inhibitor of the SHH-signalling pathway.
- Use of a combination of an inhibitor of the SHH-signalling pathway and a compound which suppresses testosterone or its effects in a patient in the manufacture of a medicament for treating a proliferative disease such as cancer in a patient.
- Use according to any one of Claims 9 to 12 wherein the inhibitor of the SHH-signalling pathway is cyclopamine or a derivative thereof.
  - 14. Use according to any one of Claims 9 to 13 wherein the compound which suppresses testosterone or its effects in the patient is any one

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or more of a GnRH antagonist, a GnRH agonist, an androgen antagonist or a  $5\alpha$  reductase inhibitor.

- 15. Use according to any one of Claims 9 to 14 wherein the patient is a male, preferably a post-pubescent male.
  - 16. Use according to any one of Claims 9 to 15 wherein the cancer is a cancer in which SHH-signalling plays a role in its growth and/or differentiation.
- 17. Use according to Claims 10 to 16 wherein the cancer is any of basal cell carcinoma, glioblastoma, medulloblastoma or prostate cancer.
- 18. A therapeutic system for treating a patient, the system comprising an inhibitor of the SHH-signalling pathway and a compound which suppresses testosterone or its effect in the patient.
- 19. A composition comprising an inhibitor of the SHH-signalling pathway and a compound which suppresses testosterone or its effect
   20 in a patient.
  - 20. A composition according to Claim 19 for use in medicine.
- A pharmaceutical composition comprising an inhibitor of the SHHsignalling pathway and a compound which suppresses testosterone
  or its effect in a patient and a pharmaceutically acceptable carrier.
- Any novel method described herein of protecting a patient from possible adverse effects of a treatment involving inhibition of the SHH-signalling pathway in the patient.

23. Any novel method described herein of treating a proliferative disease such as cancer in a patient.